



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/937,384	12/03/86	UMBECK	0501

CETUS CORPORATION
1400 FIFTY-THIRD ST.
EMERYVILLE, CA 94608

EXAMINER	
FOX-D	
ART UNIT	PAPER NUMBER
11	6

DATE MAILED: 02/03/88

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 1/27/87 ☐ This action is made final.
- A shortened statutory period for response to this action is set to expire 3 month(s), — day(s) from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input checked="" type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-22 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-22 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____
has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However,
the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are
corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO
EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in
accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

Art Unit 124

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 124.

Applicant is requested to submit a completed Form PTO 1449 in order to conform with the rules on disclosure statements. See MPEP 609.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14 and 16-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to plants and seeds comprising cells containing DNA. It is unclear whether the cells would impart a new trait or utility to the plant which would distinguish it from one occurring in nature. See Diamond v. Chakrabarty, 447 U.S. 303 (1980), Funk Bros. Seed Co. v. Kalo Inoculant Co., 233 U.S. 127 (1948), and American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931).

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is confusing as it is unclear which antibiotics may be present and which must be present.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure. The invention appears to employ novel plasmids and microorganisms. Since the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without

restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in MPEP 608.01(p)C, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocally removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Rangan et al. Rangan et al. appears to anticipate the claimed invention in its teaching of cotton somatic embryos which appear to differ from the claimed somatic embryos in source but not in kind. See MPEP 706.03(e). Thus, the claimed invention was at

least clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary, if not anticipated by Rangan et al.

Claims 14 and 16-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Adang et al. (Abstract). Adang et al. appears to anticipate the claimed invention in its teaching of transformed cotton plants which appear to differ from the claimed plants and seeds in source but not in kind. See MPEP 706.03(e). Thus, the claimed invention was at least clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary, if not anticipated by Adang et al.

Claims 14 and 16-21 are rejected under 35 U.S.C. 103 as being unpatentable over cotton plants and seeds known in the art at the time the claimed invention was made.

The claimed plants differ from those known in the art merely in the presence of cells with exogenous DNA. The mere presence of additional DNA would not render the plant unobvious unless the DNA is sufficiently expressed to provide an unexpected characteristic to the known, transformed plant. Thus, the mere transformation of a known plant was a modification within the level of ordinary skill of the art at the time the claimed invention was made such that the claimed invention was clearly prima facie obvious as a whole, in the absence of evidence to the contrary.

Claims 1-22 are rejected under 35 U.S.C. 103 as being unpatentable over DeBlock et al. taken with Zutra and Rangan et al. DeBlock et al. teaches tobacco inoculation with a non-oncogenic Agrobacterium tumefaciens comprising a first plasmid carrying the NOS promoter and exogenous CAT, MTX, and/or NPT II genes, T-DNA borders and deleted tumor genes, and a second plasmid carrying the vir region; followed by cell culture on an Agrobacterium-toxic antibiotic, which is followed by antibiotic selection of transformed cells and plant regeneration therefrom (see, e.g., page 1682, Figure 1, column 2; page 1683, column 1, second full paragraph). DeBlock et al. does not teach the inoculation of cotton hypocotyls derived from surface sterilized seed, cotton somatic embryogenesis, or the use of an exogenous gene encoding antisense RNA. Zutra teaches that cotton is a host for Agrobacterium (see, e.g., page 1200, column 3; page 1201, column 2, second paragraph). Rangan et al. teaches cotton somatic embryogenesis and plant regeneration therefrom on auxin- and cytokinin- containing media. It would have been obvious to one of ordinary skill in the art to utilize the method of non-oncogenic Agrobacterium gene transfer taught by DeBlock et al., to utilize cotton as a host, as taught by Zutra, and to utilize the method of cotton somatic embryogenesis taught by Rangan et al. to regenerate transformed plants, since each would continue to function in its known and expected manner. Choice of inoculation method would be the optimization of process parameters, as would be

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choice of exogenous gene (note applicant's admission on page 9, lines 31-35 of the specification). Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication should be directed to David Fox at telephone number 703-557-7376.


CHARLES F. WARREN
SUPERVISORY PATENT EXAMINER
GROUP ART UNIT 124

DTF

Fox:jag

A/C 703

557-3920

1/11/88